ASSURANCE OF VOLUNTARY COMPLIANCE

This Assurance of Voluntary Compliance ("AVC") is entered into by the Attorneys General of Arizona, Arkansas, California, Colorado, Delaware, the District of Columbia, Florida, Hawaii, Idaho, Illinois, Iowa, Kentucky, Louisiana, Maine, Massachusetts, Michigan, Mississippi, Missouri, Montana, Nebraska, Nevada, New Jersey, New Mexico, North Carolina, North Dakota, Ohio, Oregon, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Vermont, Washington, West Virginia, and Wisconsin, acting pursuant to their respective State Consumer Protection Laws, and Schering-Plough Corporation, Merck & Co., Inc., and MSP Singapore Company, LLC.

PREAMBLE

WHEREAS, the Multistate Working Group has initiated an investigation of the Companies with respect to the Covered Conduct;

WHEREAS, the Companies deny that they have engaged in any wrongful or unlawful conduct;

WHEREAS, the Parties have agreed to resolve the issues raised by the Covered Conduct by entering into this AVC;

WHEREAS, the Companies have voluntarily cooperated with the investigation and consented to the entry of this AVC, and have not admitted any violation of law or finding of fact;

WHEREAS, no court has entered any findings of fact or conclusions of law relating to this investigation;

IT IS on this 15th day of July, 2009 AGREED, as follows:

DEFINITIONS

1. "Companies" shall mean Schering, Merck, and MSP collectively.

2. "Covered Conduct" shall mean the Companies' promotional and marketing practices regarding the prescription drugs Vytorin® and Zetia®, the Companies' practices related to Data Safety Monitoring Boards, the Companies' publication of clinical trials and disclosure of clinical trial results, and the Companies' support of continuing medical education that were the subject of an investigation by the Signatory Attorneys General under the State Consumer Protection Laws.

3. "Effective Date" shall mean the date by which all Parties have executed the AVC.

4. "FDA Amendments Act of 2007 ("or FDA Amendments Act" or "the Act") shall mean Public Law No. 110-85, which, among other things, creates a federal clinical trial registry and results data bank.

5. "FDA's Guidances for Industry" shall mean documents published by the United States Department of Health and Human Services, Food and Drug Administration (FDA), that represent the FDA's current recommendations on a topic.

6. "Individual States" and "State" shall mean each Signatory Attorney General who is participating in the Multistate Working Group.

7. "Joint Venture(s)" shall mean any entity in which Merck or Schering maintains a direct and/or indirect ownership interest of 50% or less on the date this Agreement is signed.

8. "Merck" shall mean Merck & Co., Inc., and its United States-based affiliates, subsidiaries, predecessors, successors, and assigns, but shall not include any Joint Ventures (as that term is defined in the prior subparagraph) except for MSP.

9. "MSP" shall mean MSP Singapore Company, LLC.

10. "Multistate Executive Committee" shall mean the Attorneys General and their staffs representing Arizona, California, the District of Columbia, Florida, Illinois, New Jersey, Ohio, Oregon, Pennsylvania, South Carolina, and Texas.

11. "Multistate Working Group" ("MSWG") shall mean the Attorneys General and their staffs representing Arizona, Arkansas, California, Colorado, Delaware, the District of Columbia, Florida, Hawaii, Idaho, Illinois, Iowa, Kentucky, Louisiana, Maine, Massachusetts, Michigan, Mississippi, Missouri, Montana, Nebraska, Nevada, New Jersey, New Mexico, North Carolina, North Dakota, Ohio, Oregon, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Vermont, West Virginia, Washington, and Wisconsin.

12. "Parties" shall mean the Companies and the Individual States.

13. "Product" shall mean any prescription drug or biological product manufactured, distributed, sold, marketed, or promoted in the United States in any way.

14. "Schering" shall mean Schering-Plough Corporation and its United States-based affiliates, subsidiaries, predecessors, successors, and assigns, but shall not include any Joint Ventures (as that term is defined in the prior subparagraph) except for MSP.

15. "Signatory Attorney(s) General" shall mean the Attorney General, or his or her designee, of each state in the Multistate Working Group.

16. "State Consumer Protection Laws" shall mean the consumer protection laws under which the Signatory Attorneys General have conducted their investigation.[1]

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[1] ARIZONA – *Arizona Consumer Fraud Act*, A.R.S. § 44-1521 *et seq.*; ARKANSAS – Deceptive Trade Practices, Ark. Code Ann. § 4-88-101, *et seq.*; CALIFORNIA – Bus. & Prof Code §§ 17200 *et seq.* and 17500 *et seq.*; COLORADO – *Colorado Consumer Protection Act*, Colo. Rev. Stat. § 6-1-101 *et seq.*; DELAWARE – *Delaware Consumer Fraud Act*, Del. CODE ANN. tit. 6, §§ 2511 to 2527; DISTRICT OF COLUMBIA, *Consumer Protection Procedures Act*, D.C. Code §§ 28-3901 *et seq.*; FLORIDA – *Florida Deceptive and Unfair Trade Practices Act, Part II*, Chapter 501, Florida Statutes, 501.001-501.164, 501.207; HAWAII – *Uniform Deceptive Trade Practice*

17. "Vytorin®" shall mean ezetimibe/simvastatin.

18. "Zetia®" shall mean ezetimibe or any product that contains ezetimibe other than Vytorin®.

ASSURANCES

19. The Companies agree that each of them shall, with respect to the products Vytorin® and Zetia®, be bound by the provisions contained in Paragraphs 2 through 4 of the Agreed Final Judgment attached hereto as Exhibit A (hereinafter "Exhibit A").

20. The Companies agree that each of them shall, with respect to the products Vytorin® and Zetia®, be bound by the provisions contained in Paragraph 8 of Exhibit A. The Companies' obligations with respect to the provisions contained in Paragraph 8 of Exhibit A shall remain in effect for six years following the Effective Date. With respect to the provisions contained in Paragraph 8 of Exhibit A, the Companies shall abide by

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Act, Haw. Rev. Stat. Chpt. 481A and Haw. 501.201 *et seq.*; IDAHO – *Consumer Protection Act*, Idaho Code Section 48-601 *et seq.*; ILLINOIS – *Consumer Fraud and Deceptive Business Practices Act*, 815 ILCS 505/2 *et seq.*; IOWA – *Iowa Consumer Fraud Act*, Iowa Code Section 714.16; KENTUCKY – *Kentucky Consumer Protection Act*, KRS Ch. 367.110, *et seq.*; LOUISIANA – *Unfair Trade-Practices and Consumer Protection Law*, LSA-R.S. 51:1401, *et seq*; MAINE – *Unfair Trade Practices Act*, 5 M.R.S.A. § 207 *et seq.*; MASSACHUSETTS – Mass. Gen. Laws c. 93A, §§ 2 and 4; MICHIGAN – *Michigan Consumer Protection Act*, MCL § 445.901 *et seq.*; MISSISSIPPI – *Mississippi Consumer Protection Act*, Miss. Code Ann. § 75-24-1 *et seq.* (1972 as amended); MISSOURI – MOST § 407.010 to 407.130; MONTANA – Montana Code Annotated 30-14-101 *et seq.*; NEBRASKA – *Uniform Deceptive Trade Practices Act*, NRS §§ 87-301 *et seq.*; NEVADA - *Deceptive Trade Practices Act*, Nevada Revised Statutes 598.0903 *et seq.*; NEW JERSEY – *New Jersey Consumer Fraud Act*, NJSA 56:8-1 *et seq.*; NEW MEXICO – NMSA 1978, § 57-12-1 *et seq.*; NORTH CAROLINA – North Carolina Unfair and Deceptive Trade Practices Act, N.C.G.S. 75-1,1, *et seq.*; North Dakota – *Unlawful Sales or Advertising Practices*, N.D. Cent. Code § 51-15-02 *et seq.*; OHIO – *Ohio Consumer Sales Practices Act*, R.C. 1345.01, *et seq.*; OREGON – *Oregon Unlawful Trade Practices Act*, ORS 646.605 *et seq.*; PENNSYLVANIA – *Pennsylvania Unfair Trade Practices and Consumer Protection Law*, 73 P.S. 201-1 *et seq.*; SOUTH CAROLINA – *South Carolina Unfair Trade Practices Act*, sections 39-5-10 *et seq.*; SOUTH DAKOTA – *South Dakota Deceptive Trade Practices and Consumer Protection*, SD ST 37-24-1, 37-24-6, 37-24-23, 37-24-31, 22-41-10; TENNESSEE – *Tennessee Consumer Protection Act*, Tenn. Code Ann. § 47-18-101 *et seq.*; TEXAS – *Texas Deceptive Trade Practices and Consumer Protection Act*, Tex. Bus. And Conn. Code 17.47, *et seq.*; VERMONT – *Consumer Fraud Act*, 9 V.S.A. §§ 2451 *et seq.*; WASHINGTON – *Unfair Business Practices/Consumer Protection Act*, RCW §§ 19.86 *et seq.*; WEST VIRGINIA – *West Virginia Consumer Credit and Protection Act*, W. Va. Code § 46A-1-101 *et seq.*; WISCONSIN – Wis Stat 100.18

(FraudulentRepresentations).

any such written recommendation when such submission is made within six years of the Effective Date.

21. The Companies agree that each of them shall, with respect to the products Vytorin® and Zetia®, be bound by the provisions contained in Paragraphs 10 through 13 of Exhibit A. The Companies' obligations with respect to the provisions contained in Paragraph 13 of Exhibit A shall remain in effect for eight years following the Effective Date. The Companies' obligations with respect to the provisions contained in Paragraph 13(b) of Exhibit A shall only apply to speakers' contracts entered into, amended to extend the contract period, or renewed after the Effective Date.

22. The Companies agree that each of them shall, with respect to the products Vytorin® and Zetia®, be bound by the provisions contained in Paragraphs 15 and 17 through 19 of Exhibit A. The provisions contained in subparagraph 15(d)(ii) of Exhibit A shall also apply to consulting relationships with Schering-Plough Research Institute. The Companies' obligations with respect to the provisions contained in Paragraph 15 of Exhibit A shall remain in effect for six years following the Effective Date.

23. Nothing in this AVC shall require the Companies to:

    a. take an action that is prohibited by the FDCA or any regulation promulgated thereunder, or by FDA; or

    b. fail to take an action that is required by the FDCA or any regulation promulgated thereunder, or by FDA. Any written or oral promotional claim subject to this AVC which is the same, or materially the same, as the language required or agreed to by the Director of DDMAC or the Director of the Center for Drug Evaluation or their authorized designees in writing shall not constitute a violation of this AVC.

24. All obligations undertaken by the Companies in this AVC shall apply prospectively, except, to the extent permitted by the National Library of Medicine, the Companies shall submit, as soon as practicable, clinical trial results to the clinical trial registry and results data bank created by the FDA Amendments Act for all "applicable clinical trials" (as that term is defined by the Act) of Vytorin® and/or Zetia® that were initiated after July 1, 2005.

25. The Companies shall be bound by the provisions of paragraphs 19 through 24 of this AVC beginning 120 days after the Effective Date.

GENERAL PROVISIONS

26. Release of Claims: By its execution of this AVC, each Individual State releases the Companies and all of their past and present subsidiaries, affiliates, predecessors and successors (collectively, the "Released Parties") from all civil claims, causes of action, damages, restitution, fines, costs, and penalties on behalf of the Individual State under the consumer protection statutes listed in footnote 1 of this AVC arising from the Covered Conduct that is the subject of this AVC.

27. Claims Reserved: Notwithstanding any term of the AVC, specifically reserved and excluded from the Release in Paragraph 26 as to any entity or person, including Released Parties, are any and all of the following:

a. Any criminal liability that any person or entity, including Released Parties, has or may have to any State;

b. Any civil or administrative liability that any person or entity, including Released Parties, has or may have to any State under any statute, regulation or rule not

expressly covered by the release in Paragraph 26 above, including but not limited to any and all of the following claims:

i. State or federal antitrust violations;

ii. Reporting practices, including "best price," "average wholesale price," or "wholesale acquisition cost";

iii. Medicaid violations, including federal Medicaid drug rebate statute violations, Medicaid fraud or abuse, and/or kickback violations related to any State's Medicaid program; and

iv. State false claims violations.

c. Any liability under the State Consumer Protection Laws which any person or entity, including Released Parties, has or may have to individual consumers or State program payors of said State, and which have not been specifically enumerated as included herein.

28. Mutual Understanding: The Parties mutually recognize the following:

a. The Companies are entering into this AVC solely for the purpose of settlement, and nothing contained herein may be taken as or construed to be an admission or concession of any violation of law, rule, or regulation, or any other matter of fact or law, or of any liability or wrongdoing, all of which the Companies expressly deny The Companies do not admit any violation of the State Consumer Protection Laws set forth in footnote 1, and do not admit any wrongdoing that was or could have been alleged by any Attorney General before the date of the AVC under those laws. No part of this AVC, including its statements and commitments, shall constitute evidence of any liability, fault, or wrongdoing by the Companies.

b. This AVC shall not be construed or used as a waiver or limitation of any defense otherwise available to the Companies in any action, or of the Companies' right to defend themselves from, or make any arguments in, any private individual or class claims or suits relating to the subject matter or terms of this AVC. This AVC is made without trial or adjudication of any issue of fact or law or finding of liability of any kind.

c. Except as expressly allowed by state law, it is the intent of the Parties that this AVC not be admissible in other cases or binding on the Companies in any respect other than in connection with the enforcement of this AVC.

d. No part of this AVC shall create a private cause of action or confer any right to any third party for violation of any federal or state statute except that a State may file an action to enforce the terms of this AVC.

29. Reimbursement for Investigative Costs: Within ten business days of the Effective Date of this AVC, the Companies shall pay a total amount of $5,400,000.00 to the Signatory Attorneys General. A portion of this amount designated by the Multistate Executive Committee in the sole discretion of that Committee shall be paid by the Companies directly to each Signatory Attorney General. Said payments shall be made in reimbursement of the Multistate Working Group's attorneys' fees and other costs of investigation and shall be put to use as permitted by state law. The State of Tennessee's share shall be used as set forth in the Agreed Final Order.

30. Compliance: For purposes of resolving disputes with respect to compliance with this AVC:

a. Should any of the Signatory Attorneys General have a reasonable basis to believe that

the Companies have engaged in a practice that violates a provision of this AVC subsequent to the Effective Date of this AVC, then such Attorney General shall notify the Companies in writing of the specific objection, identify with particularity the provisions of this AVC that the practice appears to violate, and give the Companies thirty (30) days to respond to the notification; provided, however, that a Signatory Attorney General may take any action where the Signatory Attorney General concludes that, because of the specific practice, a threat to the health or safety of the public requires immediate action.

b. Upon receipt of written notice, the Companies shall provide a good-faith written response to the Attorney General notification, containing either a statement explaining why the Companies believe they are in compliance with the AVC, or a detailed explanation of how the alleged violation occurred and a statement explaining how the Companies intend to cure the alleged breach.

c. Upon giving the Companies thirty (30) days to respond to the notification described above, the Signatory Attorney General shall also be permitted reasonable access to relevant, non-privileged, non-work product records and documents in the possession, custody, or control of the Companies that relate to the Companies' compliance with each provision of this AVC as to which cause that is legally sufficient in the State has been shown. If the Signatory Attorney General makes or requests copies of any documents during the course of that inspection, the Signatory Attorney General will provide a list of those documents to the Companies. Nothing in this paragraph shall be interpreted to limit the State's Civil Investigative Demand ("CID") or subpoena authority, to the extent such authority exists under applicable state law, and the

Companies reserve all rights with respect to a CID or subpoena issued pursuant to such authority.

d. The State may assert any claim that the Companies have violated this AVC in a separate civil action to enforce this AVC, or to seek any other relief afforded by law, only after providing the Companies an opportunity to respond to the notification described in Paragraph 30(a) above; provided, however, that a Signatory Attorney General may take any action where the Signatory Attorney General concludes that, because of the specific practice, a threat to the health or safety of the public requires immediate action.

31. Entire Agreement: This AVC and the Agreed Final Order represent the entire agreement entered into by the Parties hereto and shall bind the Parties hereto. In any action undertaken by either the Attorneys General, or any of them, or the Companies, no prior versions of this AVC, and no prior versions of any of its terms may be introduced for any purpose whatsoever.

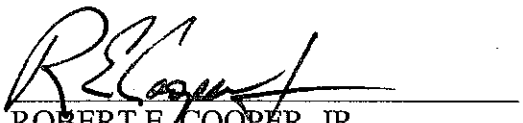
32. Modification: Any Party to the AVC may seek modification of the AVC if it believes that facts and circumstances underlying the AVC have changed in any material respect. The Multistate Executive Committee agrees to coordinate discussions with the Companies regarding any such modification and to make recommendations to the Multistate Working Group. This AVC shall be modified only by mutual assent of the parties and only by a written instrument, signed by or on behalf of the Parties, and, where required, by court order. If, after the date of entry of this AVC, an Individual State, its Attorney General, or any agency of an Individual State enacts or promulgates legislation, rules or regulations with respect to matters governed by this AVC that conflict with any provision

of this AVC, or if the applicable law of the Individual State shall otherwise change so as to conflict with any provision of this AVC, the Attorney General shall not unreasonably withhold his or her consent to the modification of such provision to the extent necessary to eliminate such conflict. Laws, rules, or regulations, or other changes in Individual State law, with respect to the matters governed by this AVC, shall not be deemed to conflict with a provision of this AVC unless the Companies cannot reasonably comply with both such law, rule, or regulation and the applicable provision of this AVC.

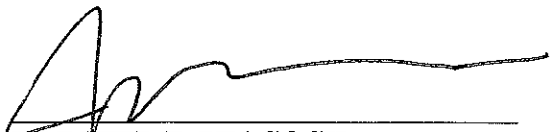
33. Severability: If any portion of this AVC is held invalid or unenforceable by operation of law, the remaining terms of this AVC shall not be affected.

34. Certification: The Parties certify that their undersigned representative is fully authorized to enter into the terms and conditions of this AVC and to legally bind the party represented.

FOR THE STATE OF TENNESSEE, ATTORNEY GENERAL:



ROBERT E. COOPER, JR.
Attorney General and Reporter
B.P.R. No. 10934



JENNIFER E. PEACOCK
Assistant Attorney General
B.P.R. No. 22227
Office of the Tennessee Attorney General
Consumer Advocate and Protection Division
425 Fifth Avenue North
Nashville, TN 37243-3400
Telephone: (615) 741-3108
Facsimile: (615) 532-2910

APPROVED:

MARY CLEMENT, DIRECTOR
Division of Consumer Affairs
Department of Commerce and Insurance
500 James Robertson Parkway
5th Floor, Davy Crockett Tower
Nashville, TN 37243-0600

FOR SCHERING-PLOUGH CORPORATION:

By: _____ Date: 7/9/09
THOMAS J. SABATINO JR.
Executive Vice President and General Counsel
Schering-Plough Corporation
2000 Galloping Hill Road
Kenilworth, New Jersey 07033

FOR MERCK & CO., INC.:

By: _____ Date: 7-9-09
BRUCE N. KUHLIK
Executive Vice President and General Counsel
Merck & Co., Inc.
One Merck Drive
Whitehouse Station, New Jersey 08889

FOR MSP SINGAPORE COMPANY, LLC:

By: _____ Date: 7-9-09
JAMES GRASTY
Vice President and Assistant General Counsel
Merck & Co., Inc.
One Merck Drive
Whitehouse Station, New Jersey 08889

By: _____ Date: 7-9-09
PD VILLARREAL
Vice President and Associate General Counsel
Schering-Plough Corporation
2000 Galloping Hill Road
Kenilworth, New Jersey 07033

By: _____ Date: 7/10/09
BRIEN T. O'CONNOR
JOAN MCPHEE
JOSHUA S. LEVY
Ropes & Gray LLP
One International Place
Boston, MA 02110-2624

Counsel to Schering-Plough Corporation,
Merck & Co., Inc., and
MSP Singapore Company LLC

By: _____ Date: 7/14/09
JAMES M. DORAN, JR.
Waller, Lansden, Dortch & Davis LLP
Nashville City Center
511 Union Street
Suite 2700
Nashville, TN 37219

Local Counsel to Schering-Plough Corporation,
Merck & Co., Inc., and
MSP Singapore Company LLC

EXHIBIT A

3

FILED
2008 JUL 15 AM 10:21
RICHARD R. ROOKER, CLERK

FILED
2009 MAY 20 AM 9:28
RICHARD R. ROOKER, CLERK

IN THE CIRCUIT COURT FOR DAVIDSON COUNTY, TENNESSEE
TWENTIETH JUDICIAL DISTRICT AT NASHVILLE

D.C.

D.C.

STATE OF TENNESSEE, *ex rel.* ROBERT E. COOPER, JR., ATTORNEY GENERAL and REPORTER,

Plaintiff,

v.

MERCK & CO., INC., a New Jersey corporation,

Defendant.

Case No. 08C-1581

AGREED FINAL JUDGMENT

Plaintiff, State of Tennessee, by and through Robert E. Cooper, Jr., the Attorney General and Reporter ("Attorney General", "State of Tennessee" or "State"), pursuant to the Tennessee Consumer Protection Act of 1977, Tenn. Code Ann. § 47-18-101 *et seq.* ("TCPA"), having filed a Complaint at the request of Mary Clement, the Director of the Division of Consumer Affairs of the Department of Commerce and Insurance ("Division"), and Defendant, Merck & Co., Inc., a New Jersey corporation, as evidenced by the signatures, consent to the entry of this Agreed Final Judgment ("Judgment") and its provisions. Whenever reference is made in this Agreed Final Judgment to "Merck" or "Defendant," these terms mean and include the use set forth in the Definitions below. Pursuant to Tenn. Code Ann. § 47-18-108, the parties voluntarily enter in this Agreed Final Judgment on the terms and conditions set forth below.

Merck expressly waives ten day notice of the Attorney General's intention to file an action pursuant to Tenn. Code Ann. § 47-18-108(a)(2). Merck hereby accepts and expressly

waives any defects in connection with service of process issued on Merck by the State and if no service has issued, Merck expressly agrees and waives the requirement that the State issue service of process of the Complaint.

Merck expressly waives and relinquishes any defense, requirement, or argument that the permanent injunction below does not contain a finding of fact or conclusion of law.

NOW THEREFORE, upon the consent of the parties hereto, **IT IS HEREBY ORDERED, ADJUDGED AND DECREED AS FOLLOWS:**

DEFINITIONS:

a. **"Covered Conduct"** shall mean Merck's promotional and marketing practices regarding the prescription drug Vioxx®, as well as Merck's practices related to Data Safety Monitoring Boards, publication of clinical trials, and the support of continuing medical education that were the subject of an investigation by the Signatory Attorneys General under the State Consumer Protection Laws. "Covered Conduct" shall not include conduct relating to promotion and marketing of the prescription drugs Vytorin® and/or Zetia® and to publication of clinical trials, practices related to Data Safety Monitoring Boards, and the support of continuing medical education, relating to Vytorin® and/or Zetia®.

b. **"Effective Date"** shall mean the date by which all Parties have executed the Agreed Final Judgment.

c. **"FDA Amendments Act of 2007"** (or **"FDA Amendments Act"** or **"the Act"**) shall mean Public Law No. 110-85 (as may be amended from time to time) which, among other things, creates a federal clinical trial registry and results data bank.

d. **"FDA's Guidances for Industry"** shall mean documents published by the United States Department of Health and Human Services, Food and Drug Administration (FDA), that represent the FDA's current recommendations on a topic.

e. **"Individual States"** and **"State"** shall mean each Signatory Attorney General who is participating in the Multistate Working Group.

f. **"Joint Venturer(s)"** shall mean any entity in which Merck maintains a direct and/or indirect ownership interest of 50% or less on the date this Agreement is signed.

g. **"Merck"** shall mean Merck & Co., Inc. and its United States-based affiliates, subsidiaries, predecessors, successors, and assigns, but shall not include any Joint Venturers (s) (as that term is defined in the prior sub-paragraph).

h. **"Multistate Executive Committee"** shall mean the Attorneys General and their staffs representing Arizona, California, Florida, Illinois, Ohio, Oregon, Pennsylvania, Texas, and Vermont.

i. **"Multistate Working Group"** or **"MSWG"** shall mean the Attorneys General and their staffs representing Arizona, Arkansas, California, Connecticut, Florida, District of Columbia, Hawaii, Idaho, Illinois, Iowa, Kansas, Maine, Maryland, Massachusetts, Michigan, Nebraska, Nevada, New Jersey, North Carolina, North Dakota, Ohio, Oregon, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Vermont, Washington, and Wisconsin.

j. **"Parties"** shall mean Merck and the Individual States.

k. **"Product"** shall mean any prescription drug or biological product manufactured, distributed, sold, marketed or promoted in the United States in any way.

l. **"Signatory Attorney(s) General"** shall mean the Attorney General, or his or her designee, of each state in the Multistate Working Group.

m. **"State Consumer Protection Laws"** shall mean the consumer protection laws under which the Signatory Attorneys General have conducted their investigation.[1]

n. **"Vioxx®"** shall mean rofecoxib.

1.

Pursuant to Tenn. Code Ann. § 47-18-108, the parties have agreed to resolve the issues raised by the Covered Conduct by entering into this Agreed Final Judgment (hereinafter "Judgment").

a. Merck is entering into this Judgment solely for the purpose of settlement, and nothing contained herein may be taken as or construed to be an admission or concession of any

[1] The States' consumer protection statutes are: ARIZONA - Consumer Fraud Act, A.R.S. § 44-1521, *et seq.*; ARKANSAS - Ark. Code Ann. § 4-88-101, *et seq.*, CALIFORNIA - Bus. & Prof. Code, §§ 17200 *et seq.*, and 17500 *et seq.*; CONNECTICUT - Conn. Gen. Stat., §§ 42-110a *et seq.*; DISTRICT OF COLUMBIA - Consumer Protection Procedures Act, D.C. Code § 28-3901, *et seq.*; HAWAII- Uniform Deceptive Trade Practice Act, Haw. Rev. Stat. Chpt. 481A and Haw. Rev. Stat. § 480-2.; FLORIDA - Deceptive and Unfair Trade Practices Act, Fla. Stat. Ch. 501.201 *et seq.*; IDAHO - Consumer Protection Act, Idaho Code Section 48-601 *et seq.*; ILLINOIS - Consumer Fraud and Deceptive Business Practices Act, 815 ILCS § 505/1 *et seq.* (2006 State Bar Edition); IOWA - Iowa Consumer Fraud Act, Iowa Code Section 714.16; KANSAS - Consumer Protection Act, K.S.A. 50-623 *et seq.*; MAINE - Unfair Trade Practices Act, 5 M.R.S.A. § 207 *et seq.*; MARYLAND - Consumer Protection Act, Md. Code Ann., Com. Law § 13-101 *et seq.*; MASSACHUSETTS - Consumer Protection Act, M.G.L. c. 93A *et seq.*; MICHIGAN - Michigan Consumer Protection Act, MCL 445.901 *et seq.*; NEBRASKA - Uniform Deceptive Trade Practices Act, NRS §§ 87-301 *et seq.*; NEW JERSEY - New Jersey Consumer Fraud Act, 56:8-1 *et seq.*; NEVADA - Deceptive Trade Practices Act, Nevada Revised Statutes 598.0903 *et seq.*; NORTH CAROLINA - Unfair and Deceptive Trade Practices Act, N.C. Gen. Stat. § 75-1.1 *et seq.*; NORTH DAKOTA -Unlawful Sales or Advertising Practices, N.D. Cent. Code. § 51-15-02 *et seq.*; OHIO- Consumer Sales Practices Act, R.C. 1345.01, *et seq.*; OREGON - Unlawful Trade Practices Act, ORS 646.605 to 646.656; PENNSYLVANIA - Unfair Trade Practices and Consumer Protection Law, 73 P.S. § 201-1 *et seq.*; SOUTH CAROLINA - Unfair Trade Practices Act, S. C. CODE. ANN. Sections 39-5-10, *et seq.*; SOUTH DAKOTA - Deceptive Trade Practices Act, S.D. Codified Laws § 37-24, *et seq.*; TENNESSEE - Tennessee Consumer Protection Act of 1977, Tenn. Code Ann. §§ 47- 18-101 *et seq.*; TEXAS - Deceptive Trade Practices - Consumer Protection Act, Tex. Bus. and Com. Code § 17.47, *et seq.*; VERMONT - Consumer Fraud Act, 9 V.S.A. § 2451 *et seq.*; WASHINGTON - Unfair Business Practices/Consumer Protection Act, R.C.W. 19.86 *et seq.*; WISCONSIN – Wis. Stat. § 100.18 (Fraudulent Representations).

violation of law, rule, or regulation, or of any other matter of fact or law, or of any liability or wrongdoing, all of which Merck expressly denies. Merck does not admit any violation of the State Consumer Protection Laws set forth in footnote 1, and does not admit any wrongdoing that was or could have been alleged by any Attorney General before the date of the Judgment under those laws. No part of this Judgment, including its statements and commitments, shall constitute evidence of any liability, fault, or wrongdoing by Merck.

b. This Judgment shall not be construed or used as a waiver or limitation of any defense otherwise available to Merck in any action, or of Merck's right to defend itself from, or make any arguments in, any private individual or class claims or suits relating to the subject matter or terms of this Judgment. This Judgment is made without trial or adjudication of any issue of fact or law or finding of liability of any kind.

c. It is the intent of the Parties that this Judgment not be admissible in other cases or binding on Merck in any respect other than in connection with the enforcement of this Judgment.

d. No part of this Judgment shall create a private cause of action or confer any right to any third party for violation of any federal or state statute except that a State may file an action to enforce the terms of this Judgment.

e. All obligations undertaken by Merck in this Judgment shall apply prospectively, except to the extent permitted by the National Library of Medicine. Merck shall submit, as soon as practicable, clinical trial results to the clinical trial registry and results data bank created by the FDA Amendments Act for all "applicable clinical trials" (as that term is defined by the Act) of FDA-approved Merck Products that were initiated after July 1, 2005.

Accordingly, pursuant to the Tennessee Consumer Protection Act of 1977, Tenn. Code Ann. § 47-18-101 *et seq.* and Tenn. Code Ann. § 47-18-108(b)(2), Merck is hereby enjoined, required and bound as set forth in the following paragraphs and sections:

2.

Merck shall register clinical trials and submit results to the registry and results data bank as required by the Amendments Act and any accompanying regulations that may be promulgated pursuant to that Act.

3.

Merck shall not make any written or oral claim that is false, misleading or deceptive regarding any FDA-approved Merck Product.

4.

Merck shall not make any written or oral promotional claims of safety or effectiveness for any FDA-approved Merck Product in a manner that violates the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FDCA"), accompanying regulations, or voluntary agreements with FDA, as interpreted by the FDA in a writing by the Director of the Center for Drug Evaluation at the FDA.

5.

A written or oral claim made by Merck in connection with a Joint Venture Product which written or oral claim has not been approved by the Joint Venture shall be subject to the provisions of Paragraphs 3 and 4. In no event, however, shall Paragraphs 3 and 4 apply to Vytorin® or Zetia®.

6.

Nothing in this Judgment shall require Merck to:

a. take an action that is prohibited by the FDCA or any regulation promulgated thereunder, or by the FDA; or

b. fail to take an action that is required by the FDCA or any regulation promulgated thereunder, or by the FDA. Any written or oral promotional claim subject to this Judgment which is the same, or materially the same, as the language required or agreed to by the Director of DDMAC or the Director of the Center for Drug Evaluation or their authorized designees in writing shall not constitute a violation of this Judgment.

7.

Merck agrees to delay direct to consumer ("DTC") television advertising for any Merck Product indicated for pain relief immediately following such Product's approval by the FDA, if the Director of the Center for Drug Evaluation at the FDA recommends such a delay in writing to Merck. Merck's delay would be for the same period as recommended by the Director of the Center for Drug Evaluation at the FDA.

8.

Merck agrees to submit all new DTC television advertising campaigns for any Merck Product to the FDA for pre-review, wait until Merck receives a response from the FDA prior to running the advertising campaign, and to modify such advertising consistent with any written comments received from the FDA.

9.

Merck's obligations with respect to Paragraph 7 shall remain in effect for ten (10) years following the Effective Date. Merck's obligations with respect to Paragraph 8 shall remain in effect for seven (7) years following the Effective Date. With respect to Paragraph 7, Merck shall abide by any such written recommendation as long as the submission of the TV advertising campaign is made within ten (10) years following the Effective Date. With respect to Paragraph

8, Merck shall abide by any such written recommendation when such submission is made within seven (7) years of the Effective Date.

10.

When presenting information in detailing pieces, brochures, booklets, mailing pieces, published journals, magazines, other periodicals and newspapers, and broadcast through media such as radio, television, the Internet, and telephone communications systems, about a Clinical Study that relates to an FDA-approved Merck Product, Merck:

a. shall accurately reflect the methodology used to conduct the Clinical Study;

b. shall not present favorable information or conclusions from a study that is inadequate in design, scope, or conduct to furnish significant support for such information or conclusions; and

c. shall not use statistical analyses and techniques on a retrospective basis to discover and cite findings not soundly supported by the study, or to suggest scientific validity and rigor for data from studies the design or protocol of which are not amenable to formal statistical evaluations.

11.

When presenting information in detailing pieces, brochures, booklets, mailing pieces, published journals, magazines, other periodicals and newspapers, and broadcast through media such as radio, television, the Internet, and telephone communications systems, about a Clinical Study or analysis of Clinical Studies as evidence of an FDA-approved Merck Product's safety, Merck shall not:

a. present information from a study in a way that implies that the study represents larger or more general experience with the drug than it actually does; nor

b. use statistics on numbers of patients, or counts of favorable results or side effects, derived from pooling data from various insignificant or dissimilar studies in a way that suggests either that such statistics are valid if they are not or that they are derived from large or significant studies supporting favorable conclusions when such is not the case.

12.

When presenting information in detailing pieces, brochures, booklets, mailing pieces, published journals, magazines, other periodicals and newspapers, and broadcast through media such as radio, television, the Internet, and telephone communications systems, about a Clinical Study or analysis of Clinical Studies as evidence of an FDA-approved Merck Product's safety, Merck shall not:

a. present favorable information or conclusions from a study that is inadequate in design, scope, or conduct to furnish significant support for such information or conclusions;

b. use the concept of statistical significance to support a claim that has not been demonstrated to have clinical significance or validity, or fails to reveal the range of variations around the quoted average results; nor

c. use statistical analyses and techniques on a retrospective basis to discover and cite findings not soundly supported by the study, or to suggest scientific validity and rigor for data from studies the design or protocol of which are not amenable to formal statistical evaluation.

13.

a. Merck shall comply with the ACCME Standards for Commercial Support, a copy of which is attached hereto as Appendix 1.

b. Any person who acts in a promotional capacity for Merck with respect to an FDA approved Merck Product shall be obligated under his or her contract with Merck, as a condition

for any future promotional relationship with Merck, to disclose to CME participants orally and to the CME provider for inclusion in the written materials the existence, nature and purpose of his or her arrangement with Merck when speaking at a CME program if:

(i) the Product the speaker promoted for Merck is in the same therapeutic category as the subject of the CME program, and

(ii) the CME program occurs within twelve (12) months of the speaker performing work for or receiving compensation from Merck. Such disclosure shall set forth the type of promotional work engaged in by the speaker and the name of the therapeutic category with respect to which such promotion was performed.

c. Merck shall not provide funding for CME when Merck has knowledge at the time the decision to fund the CME is made that a speaker at the CME has also been a promotional speaker in the past twelve (12) months at a Merck-sponsored promotional event related to the class of drugs to be discussed in the CME.

14.

Merck's obligations with respect to the CME shall remain in effect for nine (9) years following the Effective Date. Merck's obligations with respect to Paragraph 13b shall only apply to speakers' contracts entered into, amended to extend the contract period, or renewed after the date of this Judgment.

15.

All members of any external Data Safety Monitoring Board ("DSMB") constituted by Merck after the Effective Date for a Merck-Sponsored Clinical Trial shall be prohibited from:

a. holding more than $25,000 of Merck stock (exclusive of mutual fund holdings) at the time of DSMB membership;

b. trading in Merck stock during their DSMB service;

c. serving as a clinical trial investigator in the trial being monitored by the DSMB; and

d. consulting for, being employed by, or entering into any future consulting or employment relationships with Merck while serving on the DSMB, except that DSMB members may:

(i) concurrently serve on other DSMBs for Merck, and/or

(ii) consult for Merck Research Laboratories where the annual aggregate compensation for such non-promotional consulting services does not exceed Fifteen Thousand Dollars ($15,000).

16.

Merck's obligations with respect to DSMB membership set forth in Paragraph 15 shall remain in effect for DSMBs constituted within seven (7) years following the Effective Date.

17.

Merck agrees to enhance further its process for reviewing potential conflicts of interest such that all members of a DSMB shall, prior to service thereon, complete a "competing interests" form which shall include questions regarding consulting arrangements or frequent speaking arrangements with the sponsor; career involvement with a product or technique under study; hands-on participation in the trial; emotional involvement in the trial; intellectual conflicts; involvement in regulatory issues relevant to trial procedures; investment in competing products; and involvement in the publication. The forms shall carry a continued updating obligation and shall be forwarded to, and reviewed by, the DSMB chair who, in turn, will forward them to the study's Steering Committee chair or other appropriate individual for review and action, as needed, in advance of the first DSMB meeting and on an ongoing basis.

18.

Merck shall require all individuals who are named as authors on a Merck-sponsored manuscript reporting the results of a Merck-sponsored study to fulfill the following conditions:

a. the individual shall have made substantial contribution to the conception and design, or acquisition of data, or analysis and interpretation of data;

b. the individual shall have been involved in drafting the article or revising it critically for important intellectual content; and

c. the individual shall have final approval rights of the version to be published.

19.

When a large, multi-center group has conducted the research, the manuscript should identify the individuals who accept direct responsibility for the manuscript. These individuals should fully meet the criteria for authorship defined in Paragraph 18 above.

20.

By its execution of this Judgment, the State of Tennessee releases Merck and all of its past and present subsidiaries, affiliates, predecessors and successors (collectively, the "Released Parties") from the following: all civil claims, causes of action, damages, restitution, fines, costs, and penalties on behalf of the State of Tennessee under the Tennessee Consumer Protection Act of 1977, Tenn. Code Ann. § 47-18-101 *et seq.* arising from the Covered Conduct that is the subject of this Judgment.

21.

Notwithstanding any term of this Judgment, specifically reserved and excluded from the Release in Paragraph 20 as to any entity or person, including Released Parties, are any and all of the following:

a. Any criminal liability that any person or entity, including Released Parties, has or may have to the State of Tennessee.

b. Any civil or administrative liability that any person or entity, including Released Parties, has or may have to the State of Tennessee under any statute, regulation or rule not expressly covered by the release in Paragraph 20 above including, but not limited to, any and all of the following claims:

(i) State or federal antitrust violations;

(ii) Reporting practices, including "best price", "average wholesale price" or "wholesale acquisition cost;"

(iii) Medicaid violations, including federal Medicaid drug rebate statute violations, Medicaid fraud or abuse, and/or kickback violations related to any State's Medicaid program; and,

(iv) State false claims violations.

c. Any liability under the State of Tennessee's above-cited consumer protection laws which any person or entity, including Released Parties, has or may have to individual consumers or State program payors of said State, and which have not been specifically enumerated as included herein.

d. The State's right to enforce the terms of this Judgment against the Defendant for future violations of this Judgment or state law.

22.

Within ten (10) days of the Effective Date of this Judgment, Merck shall pay a total amount of **FIFTY-EIGHT MILLION DOLLARS** ($58,000,000.00) to be divided and paid by Merck directly to each Signatory Attorney General in an amount to be designated by and in the sole discretion of the Multistate Executive Committee. The State of Tennessee shall receive

ONE MILLION SIX HUNDRED EIGHT THOUSAND EIGHT HUNDRED EIGHTY-ONE AND 98/100 DOLLARS ($1,608,881.98) of this payment. The funds received by the State of Tennessee, shall be distributed and paid as follows:

a. Pursuant to Tenn. Code Ann. § 47-18-108(a)(5) and § 47-18-108(b)(4), **FIVE HUNDRED EIGHT THOUSAND EIGHT HUNDRED EIGHTY-ONE AND 98/100 DOLLARS ($508,881.98)** shall be paid to the State of Tennessee, Attorney General for attorneys' fees and costs of investigation, prosecution and monitoring for compliance of this matter, which may be used for consumer protection or other lawful purposes at discretion of the Attorney General.

b. **ONE HUNDRED THOUSAND DOLLARS ($100,000.00)** shall be paid to the State of Tennessee, Division of Consumer Affairs to fund the updating and/or purchase of new Tennessee Consumer Protection Acts for distribution to the consumers and the public, to fund consumer education project(s) selected at the sole discretion of the Director of the Division of Consumer Affairs or to fund investigations and/or litigation pursuant to the Tennessee Consumer Protection Act of 1977 selected at the sole discretion of the Director of the Division of Consumer Affairs.

c. Pursuant to Tenn. Code Ann. § 47-18-108(b) (3), **ONE MILLION DOLLARS ($1,000,000.00)** shall be paid to the State of Tennessee General Fund.

d. Any other or additional sums received by the State of Tennessee shall be paid to the State of Tennessee, Attorney General which may be used for consumer protection purposes or other lawful purposes at the sole discretion of the Attorney General.

e. If the entire amount anticipated by the State of Tennessee is not received or is received over time, any monies received shall first be attributed to attorneys' fees pursuant to paragraph 23.a, next to 23.c and finally to paragraph 23.b.

23.

For the purposes of resolving disputes with respect to compliance with this Judgment, should any of the Signatory Attorneys General have a reason to believe that Merck has engaged in a practice that violates a provision of this Judgment subsequent to the Effective Date of this Judgment, then such Attorney General shall notify Merck in writing of the specific objection, identify with particularity the provisions of this Judgment that the practice appears to violate, and give Merck thirty (30) days to respond to the notification; provided, however, that a Signatory Attorney General may take any action where the Signatory Attorney General

concludes that, because of the specific practice, a threat to the health or safety of the public requires immediate action.

Upon receipt of written notice, Merck shall provide a good-faith written response to the Attorney General notification, containing either a statement explaining why Merck believes it is in compliance with the Judgment, or a detailed explanation of how the alleged violation occurred and a statement explaining how Merck intends to cure the alleged breach.

24.

Upon giving Merck thirty (30) days to respond to the notification described above, the Signatory Attorney General shall also be permitted reasonable access to inspect and copy relevant, non-privileged, non-work product records and documents in the possession, custody or control of Merck that relate to Merck's compliance with each provision of this Judgment. If the Signatory Attorney General makes or requests copies of any documents during the course of that inspection, the Signatory Attorney General will provide a list of those documents to Merck. Nothing in this paragraph shall be interpreted to limit the State's Civil Investigative Demand ("CID"), Request for Consumer Protection Information ("Request") or subpoena authority, to the extent such authority exists under applicable state law, and Merck reserves all of its rights with respect to a CID, Request or subpoena issued pursuant to such authority.

25.

The State may assert any claim that Merck has violated this Judgment in an action to enforce this Judgment, or to seek any other relief afforded by law, only after providing Merck an opportunity to respond to the notification described in Paragraph 23 above; provided, however, that a Signatory Attorney General may take any action where the Signatory Attorney General concludes that, because of the specific practice, a threat to the health or safety of the public requires immediate action.

26.

This Judgment represents the full and complete terms of the settlement entered into by the parties hereto. In any action undertaken by any of the Attorneys General or Merck, no prior versions of this Judgment, and no prior versions of any of its terms, that were not entered by the Court in this Judgment, may be introduced for any purpose whatsoever.

27.

a. Jurisdiction of this Court over the subject matter and over the Defendant for the purpose of entering into and enforcing this Judgment is admitted. Jurisdiction is retained by this Court for the purpose of enabling the State to apply to this Court for such further orders and directions as may be necessary or appropriate for the construction, modification or execution of this Judgment, including the enforcement of compliance with this Judgment and penalties for violation thereof.

b. Pursuant to Tenn. Code Ann. § 47-18-107, venue as to all matters between the parties relating hereto shall be in Davidson County, Tennessee.

c. Nothing in this Judgment shall be construed to waive any claims of Sovereign Immunity the State may have in any action or proceeding.

d. This Judgment may only be enforced by the parties hereto.

e. Defendant has, by signature of its counsel hereto, waived any right to appeal, petition for certiorari, move to reargue or rehear or be heard in connection with any judicial proceedings upon this Judgment.

f. Nothing in this Judgment shall be construed to affect any private right of action that a consumer may hold against Defendant.

g. Nothing in this Judgment shall be construed as relieving the Defendant of the obligation to comply with all state and federal laws, regulations or rules, nor shall any of the

provisions of this Judgment be deemed to be permission to engage in any acts or practices prohibited by such law, regulation, or rule.

h. All court costs associated with this action and any other incidental costs or expenses incurred thereby shall be borne by Defendant. No costs shall be taxed to the State as provided in Tenn. Code Ann. § 47-18-116. Further, no discretionary costs shall be taxed to the State.

IT IS SO ORDERED.

DATE OF ENTRY:

CIRCUIT COURT JUDGE
TWENTIETH JUDICIAL DISTRICT

AGREED TO BY:

DEFENDANT'S SIGNATURE AND ACKNOWLEDGMENT

Defendant and its attorney have read and understand this Agreed Final Judgment and each of its terms. Defendant admits to the jurisdiction of the Court in this matter and consents to the entry of this Judgment. Defendant agrees to each and every term contained herein.

I, Bruce Kuhlik being first duly sworn on oath, depose and say that I am an officer of Merck & Co., Inc. and am fully authorized and empowered to sign this Agreed Final Judgment on behalf of Merck & Co., Inc., and bind the same to the terms hereof.

Bruce Kuhlik
Executive Vice President & General Counsel
Merck & Co., Inc.

SUBSCRIBED AND SWORN to before me this 13 day of MAY ,2008.

Notary Public
My Commission Expires:
THERESA PISARCZYK
NOTARY PUBLIC OF NEW JERSEY
MY COMMISSION EXPIRES MAR. 16, 2011

For the Defendant:
Approved as to Form

/s/James M. Doran, Jr. (TN BPR No. 2638)
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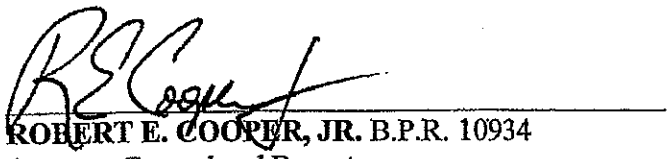
STATE OF TENNESSEE ATTORNEY GENERAL AND REPORTER:



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APPROVED AND RECOMMENDED BY:

MARY CLEMENT
Director
Tennessee Division of Consumer Affairs

APPENDIX 1

ACCME STANDARDS FOR COMMERCIAL SUPPORT℠

Standards to Ensure the Independence of CME Activities

The ACCME Standards for Commercial Support℠

Standards to Ensure Independence in CME Activities

STANDARD 1: Independence

1.1 A CME provider must ensure that the following decisions were made free of the control of a commercial interest. (See www.accme.org for a definition of a 'commercial interest' and some exemptions.)

(a) Identification of CME needs;
(b) Determination of educational objectives;
(c) Selection and presentation of content;
(d) Selection of all persons and organizations that will be in a position to control the content of the CME;
(e) Selection of educational methods;
(f) Evaluation of the activity.

1.2 A commercial interest cannot take the role of non-accredited partner in a joint sponsorship relationship.⌘

STANDARD 2: Resolution of Personal Conflicts of Interest

2.1 The provider must be able to show that everyone who is in a position to control the content of an education activity has disclosed all relevant financial relationships with any commercial interest to the provider. The ACCME defines "'relevant' financial relationships" as financial relationships in any amount occurring within the past 12 months that create a conflict of interest.

2.2 An individual who refuses to disclose relevant financial relationships will be disqualified from being a planning committee member, a teacher, or an author of CME, and cannot have control of, or responsibility for, the development, management, presentation or evaluation of the CME activity.

2.3 The provider must have implemented a mechanism to identify and resolve all conflicts of interest prior to the education activity being delivered to learners.⌘

STANDARD 3: Appropriate Use of Commercial Support

3.1 The provider must make all decisions regarding the disposition and disbursement of commercial support.

3.2 A provider cannot be required by a commercial interest to accept advice or services concerning teachers, authors, or participants or other education matters, including content, from a commercial interest as conditions of contributing funds or services.

3.3 All commercial support associated with a CME activity must be given with the full knowledge and approval of the provider.

Written agreement documenting terms of support

3.4 The terms, conditions, and purposes of the commercial support must be documented in a written agreement between the commercial supporter that includes the provider and its educational partner(s). The agreement must include the provider, even if the support is given directly to the provider's educational partner or a joint sponsor.

3.5 The written agreement must specify the commercial interest that is the source of commercial support.

3.6 Both the commercial supporter and the provider must sign the written agreement between the commercial supporter and the provider.

Expenditures for an individual providing CME

3.7 The provider must have written policies and procedures governing honoraria and reimbursement of out-of-pocket expenses for planners, teachers and authors.

3.8 The provider, the joint sponsor, or designated educational partner must pay directly any teacher or author honoraria or reimbursement of out-of-pocket expenses in compliance with the provider's written policies and procedures.

3.9 No other payment shall be given to the director of the activity, planning committee members, teachers or authors, joint sponsor, or any others involved with the supported activity.

3.10 If teachers or authors are listed on the agenda as facilitating or conducting a presentation or session, but participate in the remainder of an educational event as a learner, their expenses can be reimbursed and honoraria can be paid for their teacher or author role only.

Expenditures for learners

3.11 Social events or meals at CME activities cannot compete with or take precedence over the educational events.

3.12 The provider may not use commercial support to pay for travel, lodging, honoraria, or personal expenses for non-teacher or non-author participants of a CME activity. The provider may use commercial support to pay for travel, lodging, honoraria, or personal expenses for bona fide employees and volunteers of the provider, joint sponsor or educational partner.

Accountability

3.13 The provider must be able to produce accurate documentation detailing the receipt and expenditure of the commercial support. ⌘

STANDARD 4: Appropriate Management of Associated Commercial Promotion

4.1 Arrangements for commercial exhibits or advertisements cannot influence planning or interfere with the presentation, nor can they be a condition of the provision of commercial support for CME activities.

4.2 Product-promotion material or product-specific advertisement of any type is prohibited in or during CME activities. The juxtaposition of editorial and advertising material on the same products or subjects must be avoided. Live (staffed exhibits, presentations) or enduring (printed or electronic advertisements) promotional activities must be kept separate from CME.

- For ***print***, advertisements and promotional materials will not be interleafed within the pages of the CME content. Advertisements and promotional materials may face the first or last pages of printed CME content as long as these materials are not related to the CME content they face and are not paid for by the commercial supporters of the CME activity.
- For ***computer based***, advertisements and promotional materials will not be visible on the screen at the same time as the CME content and not interleafed between computer 'windows' or screens of the CME content
- For ***audio and video recording***, advertisements and promotional materials will not be included within the CME. There will be no 'commercial breaks.'
- For ***live, face-to-face CME***, advertisements and promotional materials cannot be displayed or distributed in the educational space immediately before, during, or after a CME activity. Providers cannot allow representatives of Commercial Interests to engage in sales or promotional activities while in the space or place of the CME activity.

4.3 Educational materials that are part of a CME activity, such as slides, abstracts and handouts, cannot contain any advertising, trade name or a product-group message.

4.4 Print or electronic information distributed about the non-CME elements of a CME activity that are not directly related to the transfer of education to the learner, such as schedules and content descriptions, may include product-promotion material or product-specific advertisement.

4.5 A provider cannot use a commercial interest as the agent providing a CME activity to learners, e.g., distribution of self-study CME activities or arranging for electronic access to CME activities. ⌘

STANDARD 5: Content and Format without Commercial Bias

5.1 The content or format of a CME activity or its related materials must promote improvements or quality in healthcare and not a specific proprietary business interest of a commercial interest.

5.2 Presentations must give a balanced view of therapeutic options. Use of generic names will contribute to this impartiality. If the CME educational material or content includes trade names, where available trade names from several companies should be used, not just trade names from a single company.⌘

STANDARD 6: Disclosures Relevant to Potential Commercial Bias

Relevant financial relationships of those with control over CME content

6.1 An individual must disclose to learners any relevant financial relationship(s), to include the following information:

- The name of the individual;
- The name of the commercial interest(s);
- The nature of the relationship the person has with each commercial interest.

6.2 For an individual with no relevant financial relationship(s) the learners must be informed that no relevant financial relationship(s) exist.

Commercial support for the CME activity.

6.3 The source of all support from commercial interests must be disclosed to learners. When commercial support is 'in-kind' the nature of the support must be disclosed to learners.

6.4 'Disclosure' must never include the use of a trade name or a product-group message.

Timing of disclosure

6.5 A provider must disclose the above information to learners prior to the beginning of the educational activity. ⌘